510(k) Summary
Prepared July 8, 2010

K102017

Sponsor: Siemens Medical Solutions, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

SEP 20 2010

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
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Submission Date: July 8, 2010

Device Name: Acuson SC2000™ Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

A. Legally Marketed Predicate Devices

The Acuson SC2000™Ultrasound System is substantially equivalent to the Acuson Sequoia Plus Ultrasound System, K072365..

B. Device Description:

The SC2000™ Diagnostic Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

The SC2000™Ultrasound System has been optimized for user ergonomics with adjustable keyboard height and rotation and independently adjustable Flat Panel Display. There is an available off-line workstation (SC2000WP)

C. Intended Use

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications.The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during neurological intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate Acuson Sequoia™ previously cleared under K063085 and K051139 and the Sequoia™ Plus Diagnostic Ultrasound System previously cleared under K072365 with regard to both intended use and technological characteristics.

E. Performance Data

The SC2000™is designed, verified, and validated according to the company's design control process and has been subjected to extensive safety and performance testing before release. Final testing of the SC2000 included various safety and performance testing designed to ensure the device meets all of its specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards including:

The Acuson SC2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

SEP 2 0 2010

Re: K102017
Trade/Device Name: SC2000™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 26, 2010
Received: August 27, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SC2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

9L4	8V3c
V5M TEE	AUX CW2
4V1c	4Z1c (Apollo)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (301) 796-6541.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

1.3 Indications for Use

510(k) Number (if known):

SEP 20 2010

Device Name: SC2000™ Diagnostic Ultrasound System

Indications for Use:

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications.The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during neurological intraoperative procedures.

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Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102017

1.3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SC2000 Diagnostic Ultrasound System**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		N	N	N	N	N	N		N*	N	N	N
Abdominal												
Intraoperative Abdominal												
Intraoperative Neurological		P	P	P		P	P	P	P*	P		
Pediatric		P	P	P	P	P	P		P	P	P	P
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic		P	P	P	P	P	P		P*	P		
Cardiac		P	P	P	P	P	P		P*	P	P	P
Trans-esophageal		P	P	P	P	P			P*		P	
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vessel		P	P	P		P	P	P	P*	P		
Laparoscopic												
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P		
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P		
Other (specify)**		P	P	P	P	P	P		P**	P		

N=new indication. P = Previously Cleared in 510(k) K063085; K072365; K051139

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**neonatal cardiac

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Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9L4**

Indications for Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological		P	P	P		P	P	P	P*	P
Pediatric										
Small Organ ** (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P		P	P	P	P*	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P
Other (specify)										

N=new indication. P = Previously Cleared in 510(k) K063085; K072365

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5M TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K063085; K072365

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510K 1C102017

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P *	P
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K063085; K072365

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V3c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K063085; K072365

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AUX CW2**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					P					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication. Previously Cleared in 510(k) K072365; K063085; K001400

Additional Comments:

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Prescription Use (Per 21 CFR 801.109)

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510K 1C102017

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4Z1c (Apollo)**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal		P	P	P	P	P			P*	P	P
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)***											

N=new indication. P = Previously Cleared in 510(k) K072365; K051139

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

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